EXHIBIT 4

The Invisalign® System

Edited by

Orhan C. Tuncay, DMD

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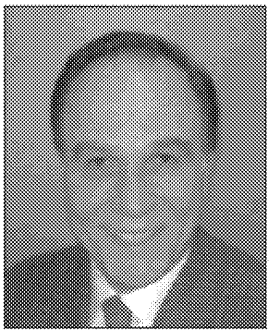
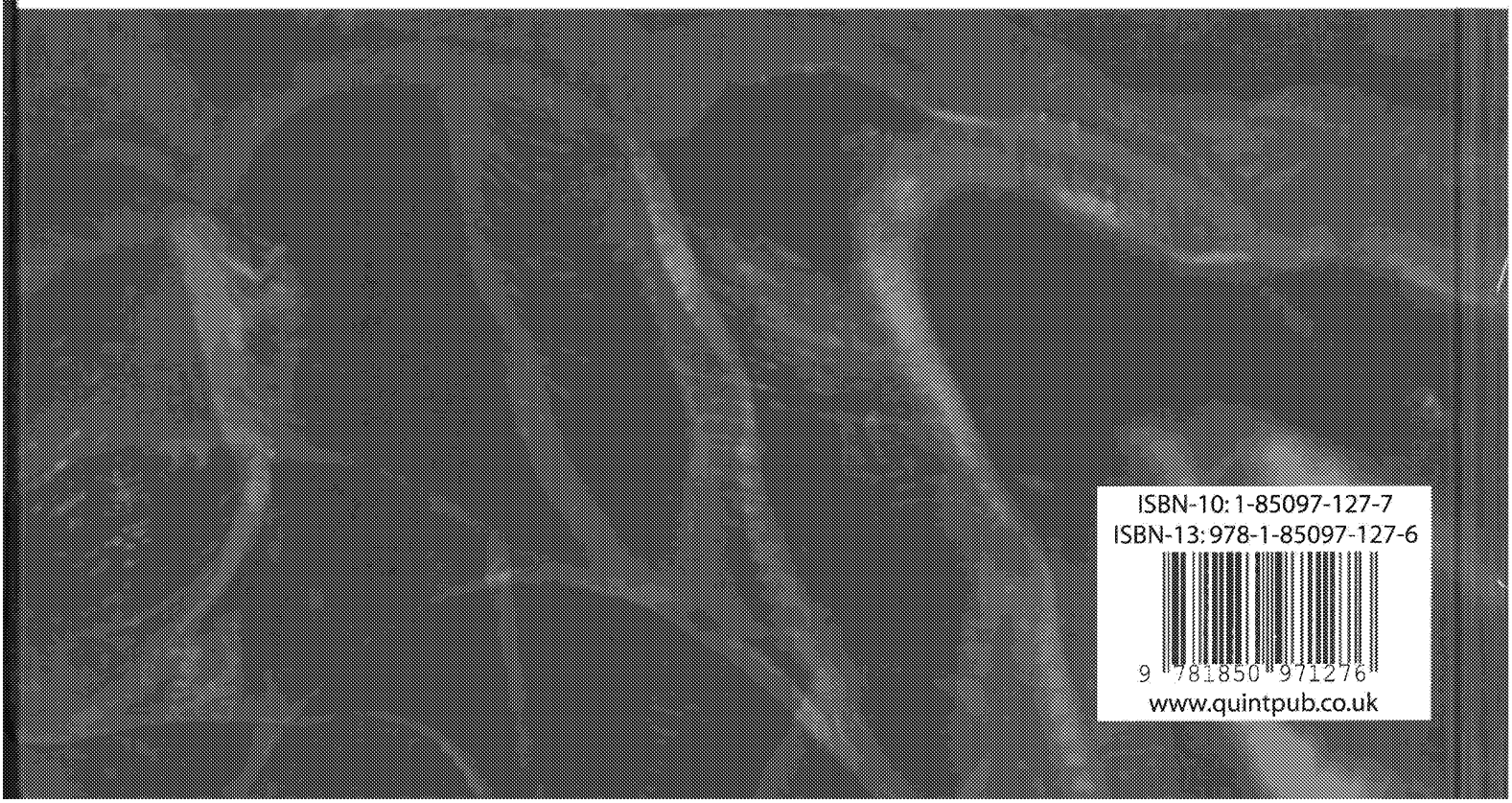


Orhan C. Tuncay, DMD, currently serves as chairman of the Department of Orthodontics and director of the graduate program at Temple University in Philadelphia, Pennsylvania. A member of the Academic Advisory Board of Align Technology, Dr Tuncay has been involved in the development of the Invisalign System since its inception, and his private orthodontic practice is devoted exclusively to Invisalign treatment. He earned his dental degrees from the University of Ankara, Turkey, and Temple University and received his orthodontic training at the University of Pennsylvania. Upon completion of his studies, he served as chairman of the Department of Orthodontics at the University of Kentucky in Lexington and subsequently held the same position at the University of Mississippi in Jackson. Dr Tuncay is the founding editor of four periodicals and the author of nearly 200 publications in the clinical and scientific literature. He is a diplomate of the American Board of Orthodontics and an active member of numerous scientific and professional organizations, having formerly held such notable positions as chairman of the Council on Scientific Affairs of the AAO, president of the Greater Philadelphia Society of Orthodontists, and president of the Craniofacial Biology Group of the IADR/AADR. Recently, the AAO Foundation honored Dr Tuncay by establishing a fellowship in his name.



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The Invisalign System

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chapter 12

STAGING

by
Rene Sterental, DDS

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Staging is the collection of steps and procedures used to arrive—in sound clinical and biologic fashion—at the final desired position of the teeth using Treat software.

After receiving the final cut model from the ToothShaper technician, the setup and stage technician reads the prescription form and reviews the clinical records that were submitted with the case to determine how the clinician wants to treat the case. The technician also reviews the clinician's preferences for accomplishing the treatment goals, as well as any other details of which the clinician wants the technician to be aware.

The setup and stage technician opens the file in Treat software to begin the ClinCheck setup. The technician aligns and positions the teeth in the Treat file to their final position as determined by the clinician's treatment prescription and preferences. After the correct final position is achieved on both arches, and after the occlusion has been adjusted, two additional stages remain in the setup: stage 0 (the initial position of the teeth before any movements have been applied) and stage 1 (the final position of the teeth).

The technician proceeds to "stage" the setup—that is, set up all the intermediate steps required to guide the teeth from the initial position to the final position, taking into consideration the biologic requirements of tooth movement, the biomechanical requirements of moving teeth with aligners, and any other details that allow the technician to set up the case efficiently and effectively. After the case is staged, the virtual setup contains information on how many stages or steps are required, the velocity at which the teeth are moving (both linear and angular), the timing of the movements for each particular tooth, the amount and timing of interproximal collisions and spaces during the treatment, and the pattern of anchorage that is being used. All this information is presented in the Stage Editor window in Treat, displayed under several tabbed windows to facilitate easy access for the technician.

Stage Editor

The Stage Editor window is used to visualize and quantify how the teeth are moving and comprises seven tabbed windows that display different information. These windows are Key Frame Editor, Move Distance, Collision, Space, Overcorrection, Translation (mm), and Rotation (deg) (Fig 12-1).

Key Frame Editor

The Key Frame Editor is used to set and display, using a graphical format, the staging pattern for the selected case. Lines and key frames are used to show at what stage a particular tooth starts to move, during how many stages it moves, and at what stage it finishes moving. Any intermediate steps are also shown. The pattern used to stage the case can easily be seen and modified; any change to the number of total or individual stages for a particular movement is performed using the Key Frame Editor (Fig 12-2).

Move Distance

The Move Distance window is used to determine the speed at which the crowns of the teeth are moving. Based on the number of stages needed to complete the movement for each tooth, the speed for each movement varies. The maximum speed that a tooth is allowed to move is 0.25 mm/stage. Speeds faster than 0.25 mm/stage are highlighted in red to alert the technician that the speed is too fast and that a larger number of stages is needed for that particular movement (Fig 12-3).

Collision

The Collision window is used to visualize numerically the amount of overlap between adjacent teeth throughout the sequence of stages. The amount of overlap detected and measured by the software is used to determine when adjacent teeth collide while they are being moved. This also determines when the overlap is increased past certain predetermined values, and finally the amount of interproximal reproximation (IPR) needed to create the space that will allow those movements to be performed clinically. These collisions are usually referred to as *microcollisions* and are the reason that contacts have to be monitored clinically with unwaxed dental floss to ensure that they do not become too tight and prevent the teeth from sliding freely against each other.

Per the current Invisalign collision protocol, normal contacts are considered to be those between 0.00 and 0.05 mm; in Treat, they are displayed in black in the Collision window. IPR below 0.2 mm per contact is not allowed, so collisions between 0.06 and 0.14 are highlighted in blue to alert the technician that they need to be removed (Fig 12-4a). A maximum of 0.5 mm of IPR is allowed, unless the clinician specifically overrides it and requests more. Any

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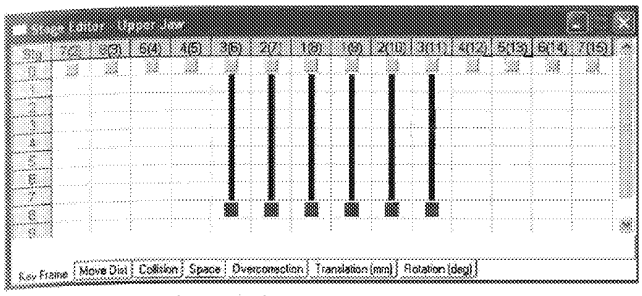

FIG 12-1 Stage Editor window.

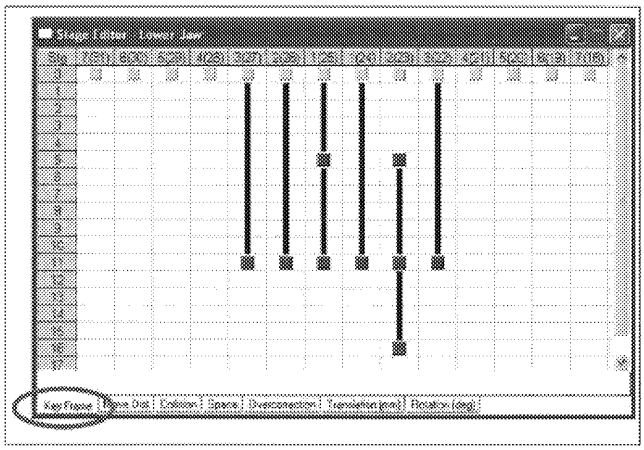

FIG 12-2 Key Frame Editor window.

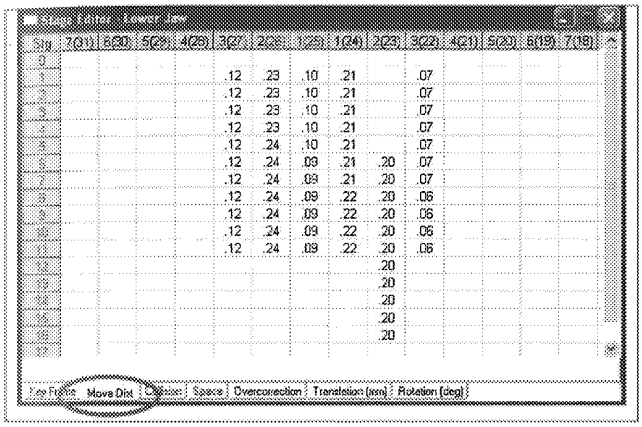

FIG 12-3 Move Distance window (velocity). Excessive velocity is highlighted in red.

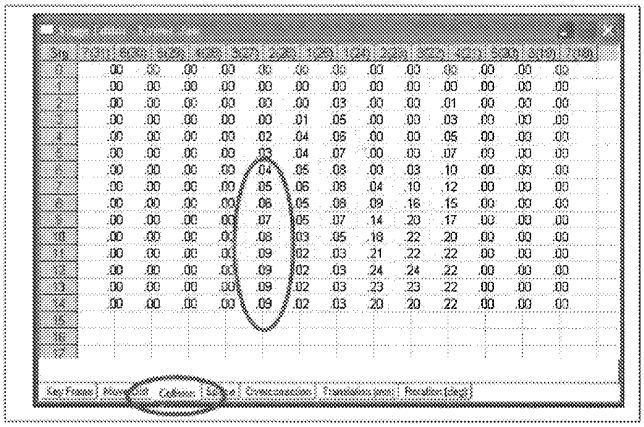

FIG 12-4a Collision window (intra-arch). Normal contacts are in black; high final collision is in blue (IPR < 0.2 mm would result).

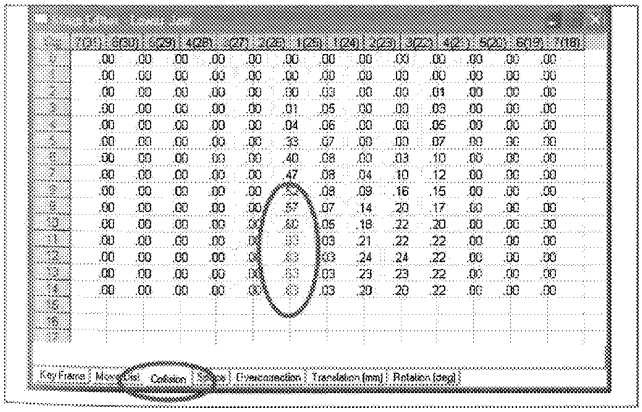

FIG 12-4b Collision window. High final collision in green (IPR > 0.5 mm would result).

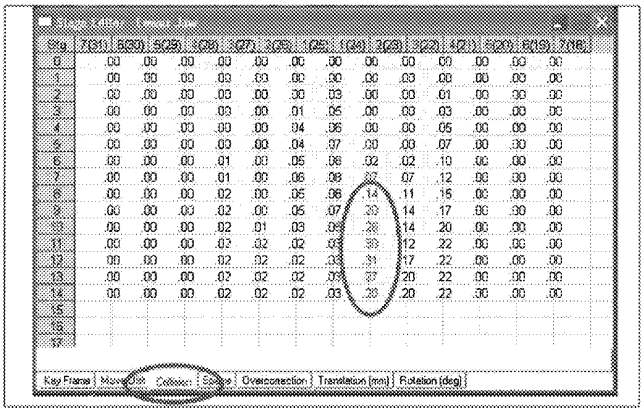

FIG 12-4c Collision window. High intermediate collisions are in red (requires intermediate key frames).

final overlap larger that 0.6 mm is highlighted in green so it is not inadvertently left unchanged by the technician (Fig 12-4b). To prevent intermediate collisions from being larger than the final overlap (which would either prevent the teeth from moving or, if IPR is performed, leave an open contact between the teeth at the end of the treatment), any overlap that is measured at 0.05 mm above the final one is highlighted in red to signal that it requires the technician's immediate attention (Fig 12-4c). Unless the clinician specifically requests that an IPR higher than 0.5 mm/contact be performed, all numbers should be black when the staging of the treatment is complete.

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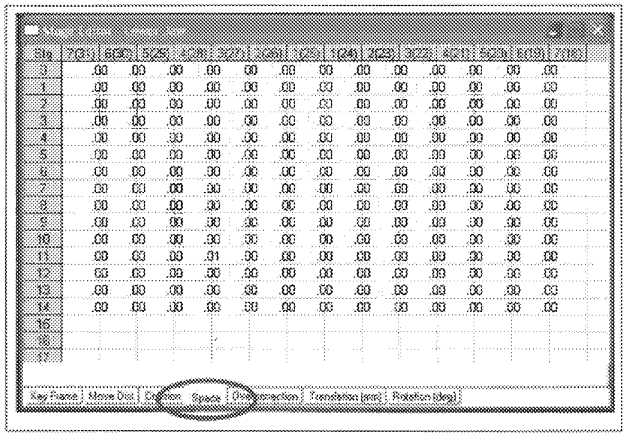

FIG 12-5 Space window.

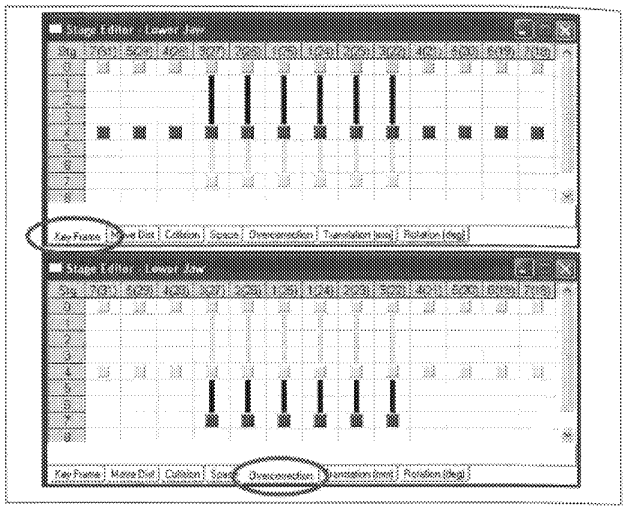

FIG 12-6 Overcorrection stages as displayed in Key Frame Editor (*top*) and the Overcorrection (*bottom*) windows.

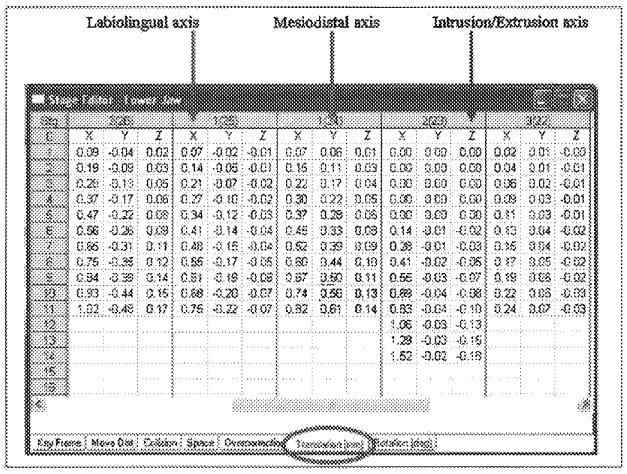

FIG 12-7 Translation window (linear movements and color correlation with widget axes).

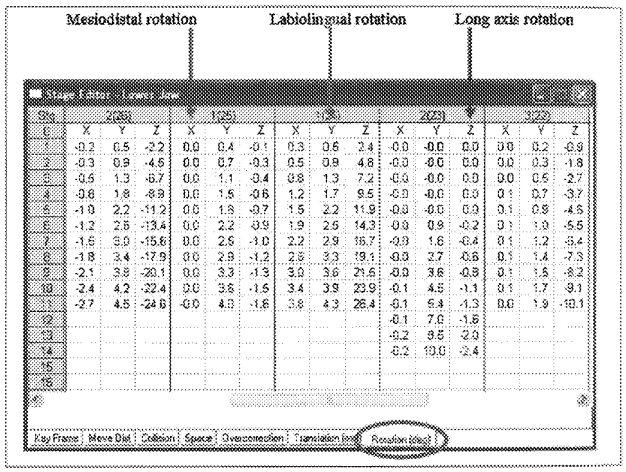

FIG 12-8 Rotation window (angular movements and color correlation with widget axes).

Space

The Space window is similar to the Collision window, except that it measures the interproximal space between the teeth (Fig 12-5). Once the teeth overlap, the space continues to read 0.00 mm. The numbers are always displayed in blue, to differentiate them at first glance from the collision numbers, which are black. Thus, an ideal contact would read "0.00" in both the Collision and Space windows. Realistically, it is not always possible to ensure good contacts at the end of the treatment. The Space window is usually used when the technician wants to make sure that the spaces required between the teeth in certain setups are equally distributed per the clinician's request.

Overcorrection

The Overcorrection window is used to stage overcorrection movements at the end of the regular treatment sequence (Fig 12-6). Overcorrection is usually performed in three stages and is designed to compensate for aligner lag and to ensure that the teeth can be moved to their final position as depicted in the virtual setup. Overcorrection is not performed in the initial setup unless it is requested and specific instructions are given by the clinician. It is always performed during case refinements (when it is clear which movements need refinement) to ensure that these movements get expressed clinically.

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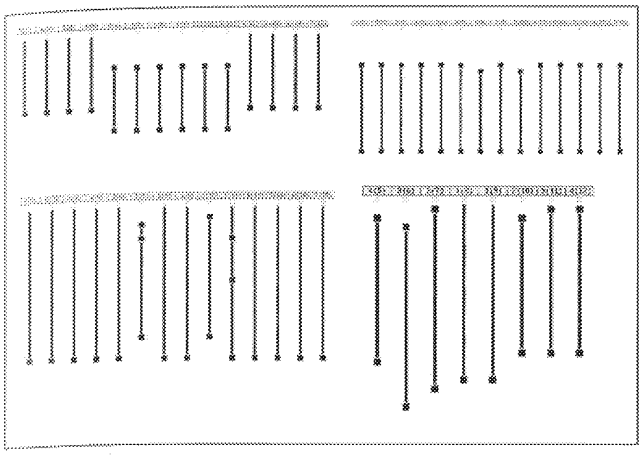

FIG 12-9a Common low-anchorage patterns.

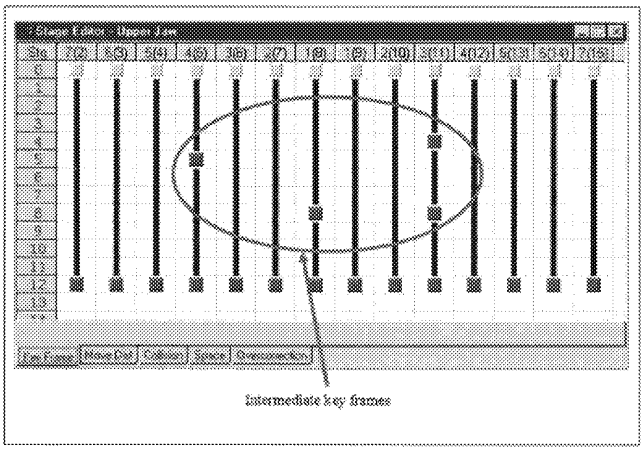

FIG 12-9b Adjusting at intermediate stages to avoid collisions.

Translation

The Translation window shows the distance that each tooth moves along the three linear axes depicted in the movement widget. These axes are the x-axis, which measures labiolingual movements along the red linear axis and is displayed under the X column; the y-axis, which measures mesiodistal movements along the green linear axis and is displayed under the Y column; and the z-axis, which measures intrusion and extrusion movements along the blue linear axis and is displayed under the Z column. The axes in the widget are shaped like arrows; if the movement is performed along the direction of the arrow's point, the number will be positive; if the movement is performed in the opposite direction, the number will be negative. A tooth can move in all three planes of space at the same time (Fig 12-7).

Rotation

The Rotation window shows the rotation that is applied to each tooth along the three rotation axes depicted in the movement widget. These rotation axes are the X rotational axis, which measures mesiodistal rotation along the red rotation axis and is displayed under the X column; the Y rotational axis, which measures labiolingual rotation along the green rotation axis and is displayed under the Y column; and the Z rotational axis, which measures rotation along the tooth's long axis along the blue rotation axis and is displayed under the Z column. If the direction of the movement is clockwise, the number will be negative; if the direction of movement is counterclockwise, the number will be positive. A tooth can rotate in all three planes of space at the same time (Fig 12-8).

Anchorage

Cases can be staged using a low-anchorage pattern or a high-anchorage pattern. This is determined based on the information contained in the doctor's prescription and diagnosis form, as well as the internal staging protocols that the technicians follow.

Low-anchorage pattern

A low-anchorage staging pattern, also known as an equal staging pattern or an "X" pattern, occurs when all the teeth move concurrently throughout the sequence (Figs 12-9a and 12-9b). The maximum velocity for tooth movement is 0.25 mm/stage, and usually all or most of the teeth are moving through all the stages at various speeds, depending on the total distance each tooth has to move. Low-anchorage patterns are usually used in Type I space closure cases, mandibular incisor extraction cases, and expansion and crowding cases where no distalization is needed. To avoid intra-arch collisions throughout the sequence of movements, intermediate key frame points can be used to manage any overlap between the teeth that may develop; these are usually added every five stages or so to ensure that the collisions remain within the protocol guidelines throughout the whole sequence. Rotations should be kept under 2 to 3 degrees per stage.

High-anchorage pattern

A high-anchorage pattern, sometimes referred to as a "V" pattern, is used when intra-arch anchorage needs to be

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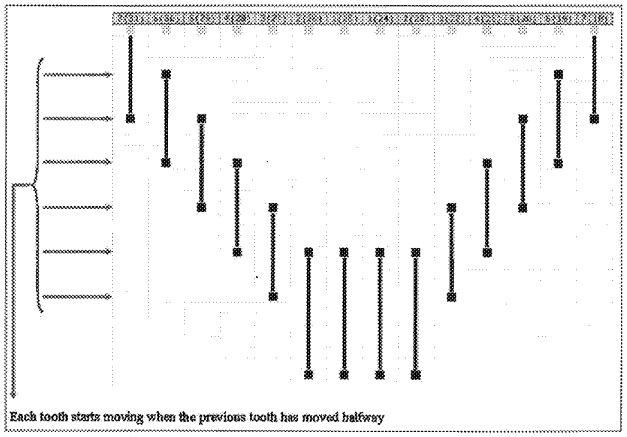

Fig 12-10a High-anchorage pattern overview.

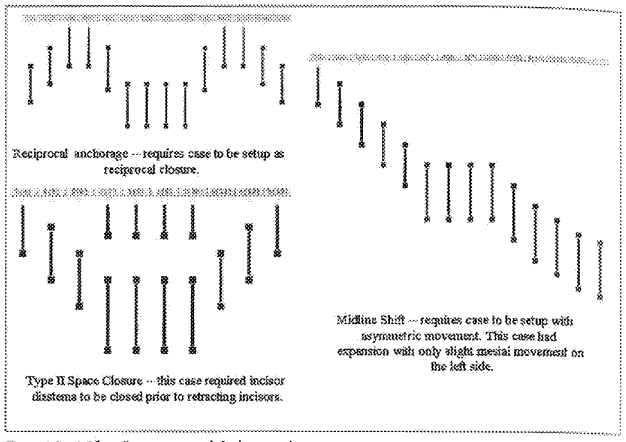

Fig 12-10b Common high-anchorage patterns.

maximized (Figs 12-10a). High-anchorage patterns are used in any case where the posterior teeth need to be distalized. It could be for Class II correction or when the relief of crowding on the anterior teeth requires that the space is created by the distal movement of the posterior teeth. This is also the case in Type II space closure cases where no mesial movement of the molars is desired. Additionally, reciprocal space closure cases where the space is closed by mesial movement of the posterior teeth (not to be confused with equal staging—minimal anchorage where no posterior mesialization is staged), and cases where a midline shift is desired, fall into this category (Fig 12-10b).

In high-anchorage patterns, only two posterior teeth can move concurrently, with the second one starting to move when the first one is halfway through its movement. The maximum speed is 0.33 mm/stage. In bilateral cases, both sides are staged symmetrically, with the number of stages determined by the teeth that are moving the most. The maximum speed for the anterior teeth remains 0.25 mm/stage.

Reproximation Calculation (Interproximal Reproximation Prescription)

Before saving the setup, or at any time during the staging, the reproximation calculation can be run to check the interproximal collisions during the staging of the case. Based on predefined parameters, the reproximation form can be created to show the clinician the interproximal contacts that will require IPR, the amount needed, and the timing of the reproximation. This information is viewed in Treat in the Reproximation Result window in a graphic manner that alerts the technicians to any potential errors. It is also sent to the clinician as an Adobe Acrobat (.pdf) file alongside the ClinCheck (Fig 12-11).

Enable Collisions

When Enable Collisions is selected, all areas where the teeth touch or overlap—both occlusally (interarch collisions) and interproximally (intra-arch collisions)—are highlighted in red. This allows the technician to visually adjust the occlusion and the contacts between the teeth, as well as visualize the areas where IPR is required in the setup. These areas can be visualized only in Treat, and are not sent to the ClinCheck (Fig 12-12).

Diagnostic Setup

A diagnostic setup is performed when the clinician checks the appropriate box in the prescription and diagnosis form. It is intended to allow the clinician and the patient to visualize in ClinCheck how one of the arches will look after the teeth are moved, but these movements are not staged in Treat so no aligners are produced. This is useful when one of the arches is being treated with fixed appliances, for example, and the clinician wants to try to match the finished result in the arch that is going to be treated with Invisalign to the intended final position of the teeth in the arch that is being treated with fixed appliances. It can also be used to show a patient how both arches will look after treatment, when the patient initially wants to treat only one arch.

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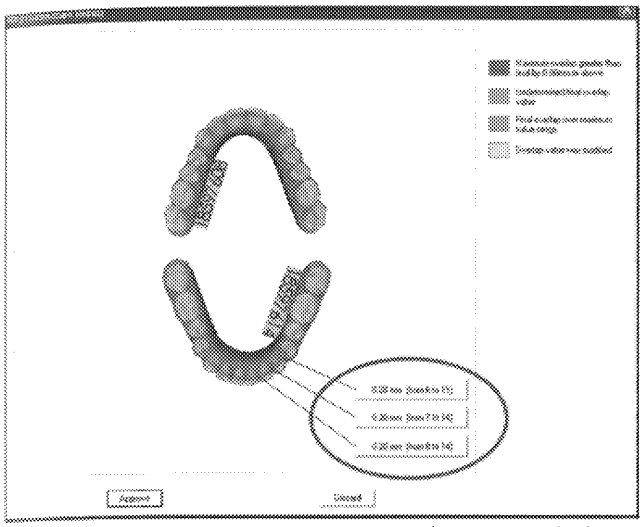


FIG 12-11 Reproximation calculation result (IPR prescription).

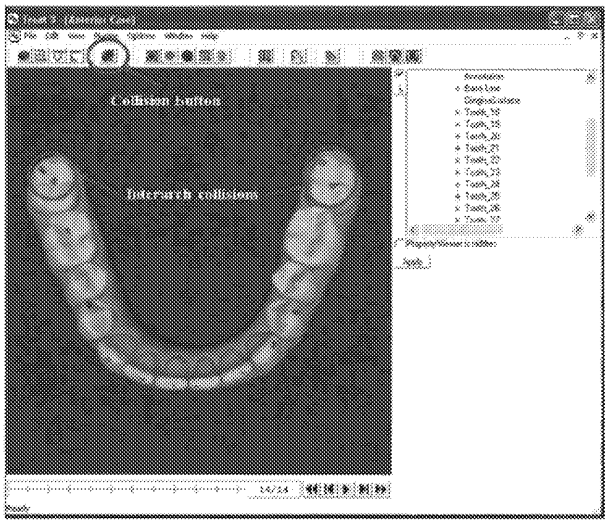
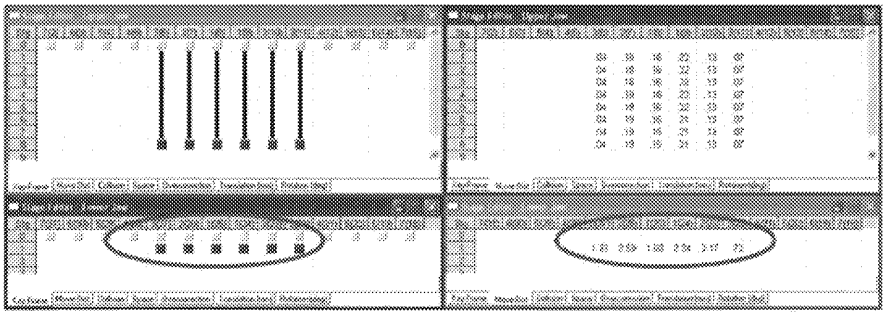


FIG 12-12 Interarch collisions enabled in Treat software (final collisions viewed).

FIG 12-13 Mandibular diagnostic setup. Key Frame Editor view (*left*) and Move Distance view (*right*). No aligners will be made for the mandibular arch.



A ClinCheck with a diagnostic setup shows one arch staged and the other arch as having only two stages: the initial stage 0 and the final stage 1 (Fig 12-13). No aligners are produced for this arch.

Surgical Setup

A surgical setup is performed in cases that require maxillofacial surgery, when the clinician wants to see that both arches are coordinated at the end of the treatment; of course, prior to actual surgery, they will not be related at occlusion. Each arch is set up and staged separately per the clinician's treatment prescription. At the end of the sequence, an additional stage is created in which both arches are occluded manually (simulating the proper occlusion that will be achieved after the surgery is performed). By doing this, the clinician can visualize the intended occlusion and confirm that both arches will be coordinated correctly (Fig 12-14).

Measuring Tools

The Treat software has several measuring tools that allow the technician to quantitatively apply the clinician's instructions. These tools also allow the technician to review the amount and type of movements being performed and determine if they are exceeding Align Technology's recommended parameters for predictable tooth movements.

Bolton Analysis Tool

The Bolton analysis tool calculates the tooth size discrepancy that is present in a case. The Bolton analysis is used to visualize the proportional relations between the maxillary and mandibular teeth in a clinically meaningful way. The Bolton analysis displays the anterior, or canine-to-canine, discrepancy and the full, or first molar–to–first molar, discrepancy (Fig 12-15).

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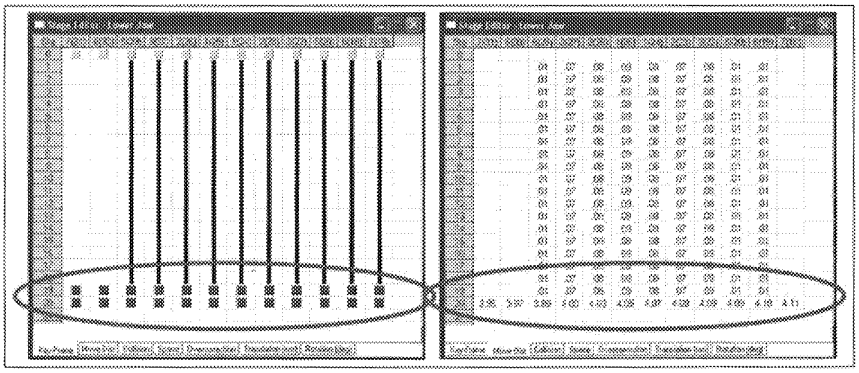

Fig 12-14 Surgical setup (mandibular repositioning). Key Frame Editor view (*left*) and Move Distance view (*right*). After stage 19, the mandible is being repositioned manually. No aligner will be made for stage 20.

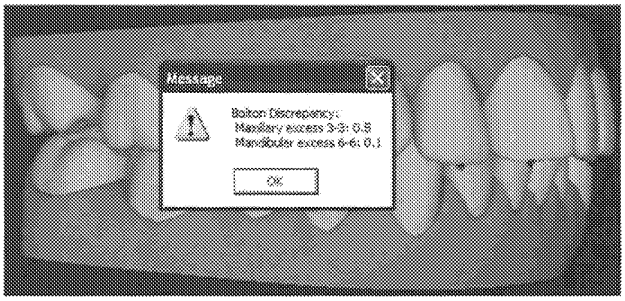

Fig 12-15 Bolton analysis in Treat software.

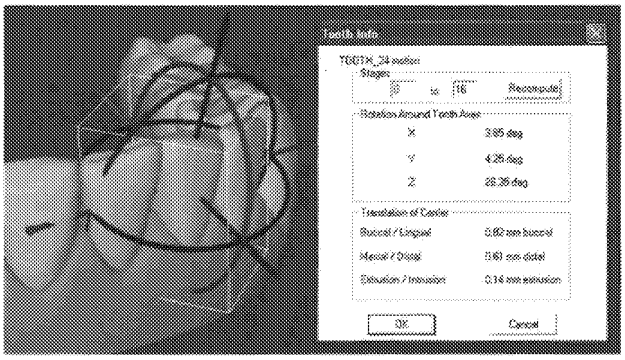

Fig 12-16 Tooth Motion Information window.

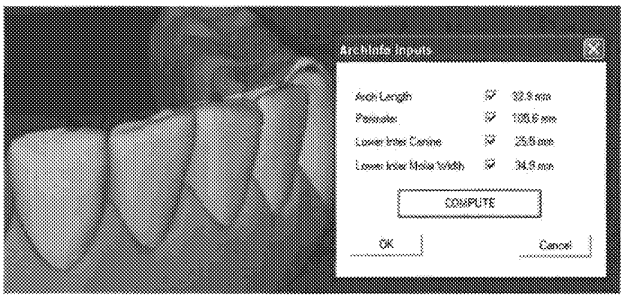

Fig 12-17 Arch Information window.

Tooth Motion Information

The Tooth Motion Information window provides a review of the clinical information on the linear movements that are being applied to the selected tooth, plus the rotation around its long axis. The measurements that are displayed include the amount of intrusion or extrusion movement, the amount of labial or lingual movement, and the amount of mesial or distal movement that are being performed, as well as the amount and direction of rotation that is being applied to the tooth around its long axis. These measurements are derived from the different axes of movement shown on the widget used to move each tooth in each particular axis (Fig 12-16).

Arch Information

When one of the arches is selected in the Treat software, the Arch Information tool allows the technician to visualize descriptive information such as arch length, perimeter, intercanine width, and intermolar width (Fig 12-17).

Attachments

Attachments are used to create a better hold for the aligner to move the teeth. They are used when the anatomy of the teeth does not provide enough undercuts for the aligner to grab the teeth solidly, to enhance the retention of the aligners to provide enough anchorage for certain movements to be expressed clinically, and to allow the aligners to apply forces in directions that they cannot otherwise achieve because of the biomechanics of the movement and the way they apply forces to the teeth. In both Treat and ClinCheck, the attachments are displayed as red

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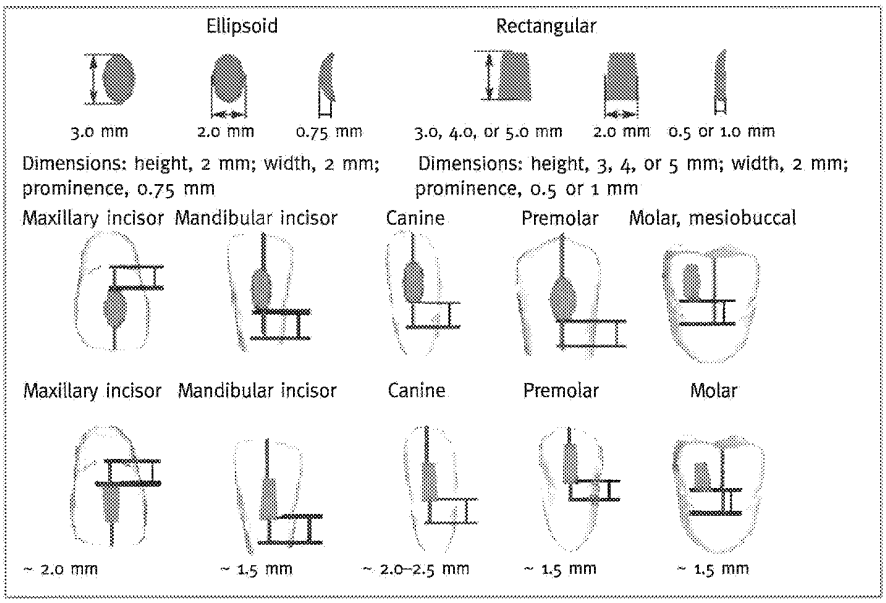

Fig 12-18 Attachment types and placement. Attachments may be requested in horizontal or vertical orientation.

shapes. They can be placed manually or automatically, per the Invisalign attachment protocol.

Currently, ellipsoid and rectangular attachments are available (Fig 12-18). Other designs are being researched, but these are not yet available to treat regular commercial cases. Clinicians can request the type and placement of attachments and can override the aligner protocol. If no requests are made, Align will only place the attachments based on what the protocol calls for. More on attachments is covered in chapter 9.

Comments

The Notepad menu item allows the technicians to write individualized comments for the clinician to review in ClinCheck or for internal use while the case is being worked on. The Notepad window has two areas, an upper area titled Comments to Customers and a lower area called Notes. Anything typed in the Comments to Customers section will be uploaded via the ClinCheck for the clinician to review; comments typed in the Notes area do not get uploaded and are intended for internal use. These comments range from preset comments designed to alert the clinician about certain aspects of the treatment to clarifications about the treatment and explanations of the reasons certain decisions were made in the course of the setup.

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